

AUG 20 2004

OFFICIAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: WARSHAWSKY=3

In re Application of:)	Conf. No.: 5740
Abraham WARSHAWSKY et al)	
Appln. No.: 10/009,300)	Attn: Office of the
Filed: May 13, 2002)	Deputy Commissioner for
For: PHARMACEUTICAL)	Patent Examination Policy
COMPOSITIONS COMPRISING)	
IRON CHELATORS FOR THE ...))	Washington, D.C.
)	August 20, 2004
)	VIA TELEFACSIMILE

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. §1.705(b)

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Mail Stop Petitions
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

Pursuant to 37 C.F.R. §1.705(b), the present application for patent term adjustment is intended as a request for reconsideration of the patent term adjustment indicated in the Notice of Allowance. The present application is being filed no later than the payment of the issue fee.

37 C.F.R. §1.705(b) (1)

The fee of \$200, as set forth in 37 C.F.R. §1.18(e), accompanies this application. If the fee submitted is deficient, or if there is no fee payment attached hereto,

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37 C.F.R. §1.705(b)(2)(i)

Applicant contends that the correct patent term in this case should be 317 days, and that the basis is 37 C.F.R. §1.702(a)(1).

37 C.F.R. §1.705(b)(2)(ii)

The relevant dates as specified in 37 C.F.R. §1.703(a) through (e) for which an adjustment is sought, and the adjustment, as specified in §1.703(f), to which the patent is entitled, are as follows:

The present application fulfilled the requirements of 35 U.S.C. §371 on May 13, 2002. The date that is 14 months thereafter is July 13, 2003. While an official action was mailed December 17, 2003, this official action was issued in error and was subsequently withdrawn. Thus, it cannot be counted as the date of mailing of an action under 35 U.S.C. §132. The first action after withdrawal of the official action of December 17, 2003, was the Notice of Allowance issued on May 25, 2004. The total number of days from July 13, 2003, through May 25, 2004, is 317 days.

The determination of patent term adjustment under 35 U.S.C. §154(b), mailed with the Notice of Allowance on May 25, 2004, states that the patent term adjustment to date is 157 days. There are 157 days between the date that is 14 months after completion of the 35 U.S.C. §371 requirement, i.e., July 13, 2003, and the date of the first (and subsequently

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withdrawn) official action, which was December 17, 2003. Thus, this time period was obviously calculated based on the date of the official action of December 17, 2003. This was erroneous, however, because this official action was mailed in error and was eventually withdrawn. Accordingly, it should not be considered to be an action under 35 U.S.C. §132, insofar as 37 C.F.R. §1.702(a)(1) is concerned.

The present national stage application under 35 U.S.C. §371 was deposited in the U.S. Patent and Trademark Office on December 7, 2001. Responsive to a notice of missing requirements issued on March 11, 2002, applicants filed a late submission of declaration, as well as a second preliminary amendment (the first preliminary amendment having been filed with the original filing of the case). The late submission was filed on May 13, 2002. A Notice of Acceptance was subsequently received, setting the date of May 13, 2002, as the date of receipt of all 35 U.S.C. §371(c)(1), (2) and (4) requirements.

On March 25, 2003, a third preliminary amendment was filed, making substantial amendments to the claims, and adding new claims 25-33.

Despite the fact that the official action of December 17, 2003, was issued almost nine months after the date of filing of the third preliminary amendment of March 25, 2003. The official action of December 17, 2003, did not

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consider the changes made by the third preliminary amendment, or the new claims added therein. Soon after the official action of December 17, 2003, was received, the undersigned tried to contact Examiner John M. Ford, who signed this official action, to ask that it be withdrawn and a new official action issued taking into account the third preliminary amendment. The examiner did not return repeated telephone calls. The undersigned periodically tried to reach the examiner for months, leaving messages on his voicemail. When the examiner never responded, the undersigned started to call his supervisor, Mr. Mukund Shah, and still received no response.

Finally, by May the frustration of the undersigned caused him to start calling examiners and staff personnel in the Group 1600 directory at random to try to find anyone who could help. Navigating the Customer Service Help Line is impossible when dealing with a specific question such as this. Director Chamber's office was called, but no quick response to the voicemail was received. It seems that she was out of the office that week. The undersigned eventually learned from another examiner that Examiner Ford had left the Office some time ago, and apparently nobody had bothered to turn off his voicemail. Furthermore, his supervisor, Mr. Shah, had been out for some time with medical problems, but this information also did not make his voicemail message. It was learned that

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Mr. James Wilson was acting SPE. A voicemail was left with him. Eventually, the undersigned contacted Ms. Rosa Thomas, who was very helpful and advised that Examiner Richard Raymond was now assigned to this case. Mr. Wilson returned the call of the undersigned soon after, and Mr. Raymond was eventually reached. At the time, the undersigned pointed out, with some distress, that no one had ever returned our phone calls over the previous several months, and that a new official action taking into account the preliminary amendment of March 25, 2003, was needed.

Finally, on May 17, 2004, Examiner Raymond agreed that the official action of December 17, 2003, failed to acknowledge and be responsive to the third preliminary amendment of May 25, 2003, and that since this amendment extensively amended the pending claims and added nine new claims, a supplemental or new action would be prepared. The examiner interview summary record with respect to this interview is of record in this case. On May 20, 2004, another telephone interview was conducted, initiated by Examiner Raymond, informing the undersigned that the claims of the application had been found to be allowable, and that a Notice of Allowance would be issued.

On May 25, 2004, a Notice of Allowance was issued in light of the amendment of March 25, 2003. While no reference to the previous official action was made in the Notice of

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Allowance, it is clear that it was withdrawn, as applicant never formally responded thereto, and the case was not deemed to be abandoned. The examiner interview statement of May 17, 2004, acknowledges that the official action of December 17, 2003, was issued in error. The issuance of the Notice of Allowance clearly had the effect of withdrawing that official action. As the official action was withdrawn, it is as if it had never issued. Therefore, it cannot serve to toll the time that it took for the Patent and Trademark Office to mail either a notification under 35 U.S.C. §132 or a Notice of Allowance under 35 U.S.C. §151.

There are no relevant dates under 37 C.F.R. §§1.703(a)(2) through (6). The number of days for each of those is zero.

As applicant does not claim any adjustment under 37 C.F.R. §§1.702(b) through (e), there are no relevant dates in 37 C.F.R. §§1.703(b) through (e), for which an adjustment is sought, nor is there any adjustment sought under 37 C.F.R. §1.703(f).

37 C.F.R. §1.705(b)(2)(iii)

The patent is not subject to a terminal disclaimer.

37 C.F.R. §1.705(b)(2)(iv)(A)

As to the circumstances during the prosecution of the application that constitute a failure to engage in

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reasonable efforts to conclude processing or examination, as set forth in §1.704, the following statements are applicable:

37 C.F.R. §1.704(b) is not applicable as applicant did not respond to any rejection, objection, argument or other request made between the date of fulfillment of the requirements under 35 U.S.C. §371 and the date of issuance of the notice of allowance. Furthermore, none of the circumstances set forth in 37 C.F.R. §§1.704(c)(1) through (11) occurred in this case. In particular, 37 C.F.R. §1.704(c)(6) is not applicable, because the preliminary amendment of March 25, 2003, was filed well over a month prior to the mailing of an Office action under 35 U.S.C. §132 or Notice of Allowance under 35 U.S.C. §151, and therefore could not have necessitated the mailing of a supplemental Office action or Notice of Allowance. Indeed, the only preliminary amendment filed during this period was that of March 25, 2003, about nine months prior to the issuance of the subsequently withdrawn official action of December 17, 2003, and fourteen months prior to the issuance of the Notice of Allowance.

The circumstances of 37 C.F.R. §§1.704(d) and (e) are also inapplicable.

37 C.F.R. §1.705(b)(iv)(B)

There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or

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examination of the application as set forth 37 C.F.R. §1.704,
for the reasons discussed above.

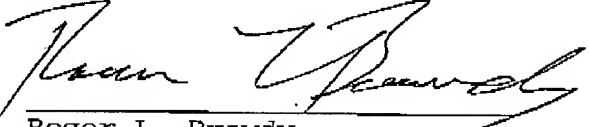
Conclusion

As applicant has complied with all of the
requirements of 37 C.F.R. §1.705(b), granting of this
application for patent term adjustment, and changing the
patent term adjustment previously set as 157 days to a total
of 317 days is earnestly solicited.

Respectfully submitted,

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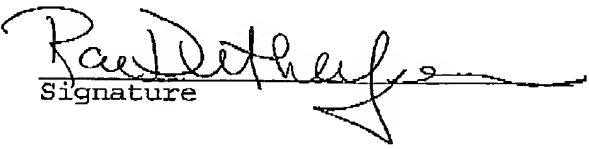
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I hereby certify that this paper is being facsimile
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on the date shown below.

Rae Dethlefsen
Name


Signature

August 20, 2004
Date